

# CLAIMS

1. An implant for implantation in a middle-ear chamber, said implant comprising:  
a pliant membrane formed into a balloon, said balloon configured to fit within said middle-ear chamber and to contact an eardrum, said pliant membrane being selected to form a balloon having an acoustic impedance low enough to permit said eardrum to respond to incident acoustic waves.
2. The implant of claim 1, wherein said pliant membrane forms a balloon having an acoustic impedance corresponding to an equivalent volume of at least 70%.
3. The implant of claim 1, wherein said implant further comprises a tab extending from an end of said balloon.
4. The implant of claim 3 wherein said tab includes a radio-opaque marker.
5. The implant of claim 1, wherein said balloon is an ovaloid having a maximum dimension along a principal axis extending between a first end and a second end, and said implant further comprises a tab extending from at least one of said first and second ends.
6. The implant of claim 5, wherein said balloon is dimensioned to be positioned by surrounding structures within said middle-ear chamber and to displace fluid and soft tissue therefrom, thereby forming a compliant cushion presenting low acoustic impedance to motion of said eardrum.
7. The implant of claim 1, wherein said pliant membrane comprises polymer of vinylidene chloride (PVDC).
8. The implant of claim 1, wherein said pliant membrane comprises a biocompatible material.
9. The implant of claim 8, wherein said biocompatible material is a polymeric film

free of toxic additives.

10. The implant of claim 8 wherein said pliant membrane is a multilayer membrane and said biocompatible material forms an outermost layer of said multilayer membrane, said outermost layer being exposed, upon implantation of said implant, to the interior of said middle-ear chamber.
11. The implant of claim 1, wherein said pliant membrane is substantially impermeable to water, gases and body fluids during protracted contact with body tissues.
12. The implant of claim 1 wherein said balloon contains at least one naturally occurring gas.
13. The implant of claim 1 wherein said balloon contains at least one non-naturally occurring gas.
14. The implant of claim 13, wherein said non-naturally occurring gas is a large molecular size gas which is non-toxic and to which said pliant membrane is substantially impermeable.
15. The implant of claim 13, wherein said non-naturally occurring gas is sulfur hexafluoride.
16. The implant of claim 1, wherein said balloon contains a gas mixture at atmospheric pressure.
17. The implant of claim 1, wherein said balloon contains a gas mixture having a pressure in the range of approximately 50 mm of water below atmospheric pressure to approximately 50 mm of water above atmospheric pressure.
18. The implant of claim 1, further comprising means for self-inflating said balloon, said self-inflating means including gas at sub-atmospheric pressure effective for self-inflation by diffusion following implantation of said implant into said middle-ear chamber.

19. The implant of claim 1 further comprising means for initiating self-inflation following implantation, said means for initiating self-inflation including gases at partial pressures effective to initiate self inflation.
20. The implant of claim 1 wherein said pliant membrane is between approximately 1 mil thick and approximately 4 mils thick.
21. An implant for implantation in a middle-ear chamber, said implant comprising:  
  - a plurality of balloons formed from a pliant membrane, said balloons configured to fit within said middle-ear chamber with at least one of said balloons at least partially in contact with the eardrum, each of said balloons having an acoustic impedance low enough to permit said eardrum to respond to incident acoustic waves.
22. A surgical method for treating middle-ear hearing loss of a patient, said method comprising  
  - positioning a balloon in the patient's middle ear at least partially in contact with the eardrum, said synthetic balloon being formed of a thin pliant membrane of biocompatible material such that said balloon has an impedance low enough to permit sound-induced motions of the eardrum, ossicles and the round window membrane, said pliant membrane being substantially impermeable to water and to gases during extended contact with body tissues.
23. A surgical method according to claim 22, wherein positioning a balloon includes positioning the balloon between the eardrum and the bone covering the cochlea.
24. A surgical method according to claim 22, further comprising exposing the patient's middle ear by elevating a tympano-meatal flap before disposing said balloon in the middle ear.
25. The surgical method of claim 24, further comprising securing said balloon into position with an anchor formed of resorbable packing.

26. The surgical method of claim 22, further comprising positioning one or more additional balloons in the patient's middle-ear such that said additional balloons are mechanically coupled to said balloon.

00633-025001-1952920